REMARKS

Claims 1-12 stand cancelled without prejudice; and new claims 13-15 have been added. No new matter is presented by virtue of the within amendment. For instance, the subject matter of new claim 13-15 is supported by the description at page 3, paragraph (8), page 4, paragraph (10), page 9, lines 13-24, pages 34-36, and pages 41-42 of the specification.

The office action has indicated that the amendment filed May 24, 2004 is objected to under 35 U.S.C. §132 because it allegedly introduces new matter into the disclosure.

Applicants respectfully submit that the claims presented in the instant amendment are fully supported by the original disclosure. See, for example, the claims as originally filed, the acceptable sequence homology for the ligand peptide recited at page 9, lines 13-24 and the assay for identifying compounds capable of binding to G protein-coupled receptor protein

In view of the above, Applicant submits that new claims 13-15, satisfy the written description requirement, and respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Claims 1-3, 6 and 11 stand rejected under 35 USC §112, second paragraph, for various informalities and certain aspects allegedly requiring clarification.

It is believed that the within amendments obviate the rejection. For instance, new claim 13 provides that the G protein-coupled receptor protein phGR3 is selected from those sequences having at least 95% identity with SEQ ID NO. 44. Still further, throughout the specification the term "oxytocin secretion promoter" is described and utilized as one of the "oxytocin secretion regulators". Thus, it is believed that the within amendments obviate each of the rejections under

35 USC §112, 2nd paragraph. Thus, reconsideration and withdrawal of the rejection are requested.

Claims 1-3 and 6 were rejected under 35 USC 112, 1st paragraph, allegedly for lack of enablement. Claims 1-2, and 6 also stand rejected under 35 USC 112, 1st paragraph, allegedly as lacking adequate written description.

The Office Action expressly acknowledges that the specification is enabling for an isolated and purified oxytocin secretion regulator, comprising a ligand peptide which has the amino acid sequence represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44, or a salt thereof, for G protein-coupled receptors phGR3 and UHR-1. However, the position is taken that the specification does not reasonably provide enablement for other oxytocin secretion regulators.

Although applicants respectfully disagree with the position taken by the Examiner in the last office action, the claims have been reformulated to methods of regulating oxytocin secretion using an isolated and purified oxytocin secretion regulator, comprising a ligand peptide, or salt thereof, for a G protein-coupled receptor protein, phGR3, wherein the ligand peptide, or salt thereof, for a G protein-coupled receptor protein is a polypeptide, or an amide or an ester or a salt thereof, containing an amino acid sequence that has at least 90% sequence homology to the amino acid sequence represented by SEQ ID NO: 44.

Applicant submits that claim 13, as presented, complies with the written description requirement. As set forth in Example 14 of the Written Description Guidelines, the written description is satisfied for variants that are at least 95% identical to the reference sequence (i.e., SEQ ID NO:44), and which retain the disclosed functional activity (i.e., oxytocin secretion regulation), when the procedures for making such variants are conventional in the art, and when

the specification discloses an assay which will identify proteins having the claimed catalytic activity.

Applicant further submits that procedures for making nucleotide and protein variants were well-known at the time the invention was made. Applicant further submits that a assay for the identification of compounds (including peptides) capable of altering the biding of a labeled ligand and the receptor protein is described at least at pages 34-36 and pages 41-42. Thus, the invention provides methods of identifying those peptides having at least 90 % sequence homology (or 95% identity) with SEQ ID NO. 44 which possess oxytocin secretion regulation activity.

Claims 1-3 and 6 stand rejected under 35 USC §102(b), over WO 97/24436 to Takeda Chemical Industries Ltd. The Office Action asserts that WO 97/24436 discloses an amino acid sequence which has 100% sequence identity to the amino acid sequence represented by SEQ ID NO: 3, 18, 32 and 44 of the present application.

Although Applicants respectfully disagree with the position taken by the Office Action, the claims, as amended, provide methods of regulating oxytocin secretion. None of the cited art of record in the instant application, taken alone or in combination, teach or suggest the instantly claimed methods.

It is believed the application is in condition for immediate allowance, which action is earnestly solicited.

Respectfully submitted,

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